REMARKS/ARGUMENTS

Claims 1, 3, 5, and 7-15 remain in this application. Claims 28-39 have been withdrawn due to a restriction requirement wherein the Applicants have elected to prosecute Group I (claims 1, 3, 5, and 7-15).

Claims 1, 3, 5, and 7-11 have been amended to more particularly claim that which the inventors consider to be the invention. These amendments are supported throughout the specification and do not represent new matter.

35 U.S.C. 112, First Paragraph (written description)

Claims 1, 3, 5, 7-15 are rejected under 35 U.S.C. 112, first paragraph as allegedly containing subject matter that is not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors had possession of the claimed invention at the time of the application. In particular, it is alleged that the specification and claims do not indicate what "distinguishing attributes" are shared by the members of the subject matter of the claims, *i.e.*, a nucleic acid genus. And further, it is alleged that there is no common 'structural attributes' given to identify the members of the claimed genus. It is concluded that the disclosure fails to provide a representative number of species to describe the claimed genus and therefore the Applicants were not in possession of the claimed invention.

Applicants' representative traverses this rejection for the following reasons.

In the recent Enzo decision (*Enzo Biochem, Inc. v. Gen-Probe Inc.*, No. 01-1230 (Fed Circ., 2002)), the Federal Circuit reviewed with approval the Office's guidelines on written description. In particular, the Court considered claims to antibodies directed to a particular antigen, where no antibodies had been described. In this type of claim there is no structure given in which there is a common structural or distinguishing attribute, as is now required by the present Examiner in order for there to be sufficient written description of the presently claimed invention. However, the Court noted that this type of claim can be sufficient for the purposes of written description when the function of a claimed molecule is sufficient to describe the molecule when the antigen is known. This is particularly true in fields that are developed and mature, such as in antibody/antigen interactions and can be extended to additionally well characterized fields such as ligand/receptor binding which is, like antibody/antigen binding, another example of a protein binding a second protein.

The presently claimed invention encompasses a description of a molecule partly by it's function, i.e., capable of binding its receptor, hek. In addition, the claims also provide additional limitations on the scope of the molecules that can be included in the claimed genus, i.e., at east 80% identity to a known sequence. Thus, the common attributes of the claimed genus are 80% identity to a prescribed sequence, *e.g.*, SEQ ID Nos 1 or 3, **and** encoding a protein that has the ability to bind hek. This type of claim language, in view of the teachings of the specification, is completely consistent with *Enzo* and therefore, the claimed invention meets the written description requirement.

It is believed that these two attributes are more than sufficient to meet the written description requirement. It is also noted that claims similar to these are routinely allowed to issue by the Office. However, if the Office finds that these are still insufficient, Applicants' representative request clarification of examples of what would suffice to meet the appropriate standard. Accordingly, in view of the above arguments, applicant respectfully submits that the foregoing rejection is in error and should be withdrawn for the reasons cited.

35 U.S.C. 112, First Paragraph (enablement)

Claims 1, 3, 5, 7-15 are rejected under 35 U.S.C. 112, first paragraph as allegedly not enabling for isolated DNA encoding a hek-L protein that is at least 80% identical to a sequence as set forth in SEQ ID Nos 1 or 3. Further, it is stated that there are no actual or prophetic examples on the expected 'parameters of any of the possible nucleic acid molecules encoding muteins of hek-L' polypeptides.

Applicants' representative traverses this rejection for the following reasons.

The test for enablement is whether one reasonably skilled in the art could make or use the invention, without undue experimentation, based on the teachings of the specification coupled with information known in the art at the time the patent application was filed. *U.S. v. Telectronics Inc.*, 857 F.2d 778, 8 U.S.P.Q.2d 1217 (Fed. Cir. 1988). Enablement is not precluded even if some experimentation is necessary. *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986). This is so even if the amount of experimentation is laborious. [emphasis added] *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988). Further, the Courts have held that the key word is "'undue', not 'experimentation." *In re Angstadt*, 190 U.S.P.Q. 214 (C.C.P.A. 1976).

In *In re Wands*, the Applicants claimed an assay using any monoclonal antibody that had a high affinity for an antigen. The Applicants used techniques well known in the art to make over 100 monoclonal antibodies. However, it was impossible to predict which of these antibodies would recognize the antigen and which would not without subsequent testing. The Federal Circuit held that even though there was additional testing that would be required to determine the full scope of the claimed invention, it would not constitute undue experimentation. This is analogous to the present situation, where the inventors have set forth a genus of molecules that would need to be tested for their ability to encode a protein capable of binding hek. The type of experimentation required to show a protein interaction, however, is routine as would be recognized by one of skill in the art and is also shown in the examples of the present specification. Therefore, it is respectfully submitted that the amount of experimentation required to enable the claimed invention is not undue.

Indeed, the specification teaches mutant sequences having additions or deletions (pp. 5-7), the regions of the hek-L which are important for ligand-receptor interaction (namely, the extracellular domain, p. 7), and assays for measuring binding of hek-L to its receptor (pp. 11-13 and Example 5 on pp. 29-31).

Thus, the amount of teaching provided is more than sufficient to provide enablement to conduct any secondary experimentation. Given the teaching of the specification and the level of skill in the art, the effort required to perform the experiments would be merely routine, and the amount of work needed for determination of the nucleic acids encoding the desired polypeptides would not be undue. Thus, these teachings, considered in light of the above described law are sufficient to enable one of skill in the art to practice the invention without undue experimentation.

The Examiner further objects to the lack of more working examples. However, as long as the specification teaches how to make and use the invention, a particular number or content of illustrative examples are not required. Enablement is met by an objective standard, and therefore one need not teach, and preferably omits, what is well known in the art. *Staehelin v. Secher*, 24 U.S.P.Q.2d 1513, (B.P.A.I. 1992) ("How such a teaching is set forth, whether by the use of illustrative examples or by broad descriptive terminology, is of no importance").

Thus, in light of the teachings of how to use the invention, it should not be held that the presently claimed invention is not enabled and withdrawal of this rejection is respectfully requested.

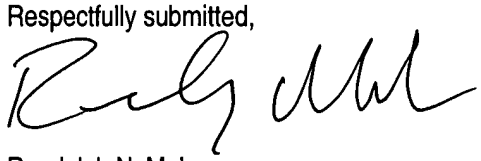
Obviousness-Type Double Patenting

Claims 1, 3, 5, 7-15 are rejected under the judicially created doctrine of obviousness-type double patenting. It is stated that a terminal disclaimer can be filed to overcome statutory double patenting providing the conflicting application and patent are commonly owned. The cited patent, U.S. Patent No. 5,516,658 is indeed commonly owned with the instant application. It is respectfully submitted that a terminal disclaimer will be filed when the Examiner has indicated that the rejections under section 112 are overcome, and the application is in form for allowance.

CONCLUSION

Applicants respectfully submit that the claimed invention of the present application is in proper condition for allowance, and respectfully requests issuance thereto. The Examiner is encouraged to telephone the undersigned in order to resolve any outstanding issues in the present application and to facilitate its prosecution.

Respectfully submitted,



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